Attorney Docket No.: B0410/7269D2

Filed: January 29, 2004 Amendment and Reply

# REMARKS

U.S. App. No. 10/767,550

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Inventors: Richard A. Gambale et al.

The examiner has indicated that the application is in condition for allowance except for corrections to the disclosure, drawings and claims. Specifically, the disclosure (specification and drawings) is objected to because it incorporates reference material found in unpublished application U.S. App. No. 09/073,118 ("the '118 application"). The action requires applicant to incorporate the material showing the steerable aspects of the catheter.

The specification and drawings are amended. The amendments are based on the '118 application, which was previously incorporated by reference at page 15, lines 25-28 of the present application. Claim 30 is amended as requested in the action to correct a minor typographical error. No new matter is added.

### Objections to the Specification

The action states that the present disclosure incorporates by reference essential material relating to the steerable delivery catheter. 37 C.F.R.§1.57 states that such material must be incorporated by amendment. Accordingly, the paragraph at page 15, lines 9-28 has been amended based on the text from the '118 application describing a steerable delivery catheter, which is found on page 16, lines 1-13 of the '118 application. A copy of page 16 of the '118 application is filed herewith as Exhibit A, for the examiner's convenience.

The amendments refer to new drawing FIG. 4E, which shows a steerable catheter as presented in the '118 application, including pull wire 35, pull wire lumen 37 and bond 39 attaching the pull wire to the distal end of the pull wire lumen.

The specification has also been amended to include the description of new FIG. 4E. Entry of the amendments is respectfully requested.

#### Objections to the Drawings

The action states that the present disclosure incorporates by reference essential material relating to the steerable delivery catheter. 37 C.F.R. §1.57 states that such material must be incorporated by amendment.

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## Amendments to the Drawings:

The attached single drawing sheet includes new drawing FIG. 4E. FIGS. 4A-4D are unchanged.

Also enclosed as Exhibit B is a marked-up copy of FIG. 11A from U.S. App. No. 09/073,118, on which new drawing FIG. 4E is based. U.S. App. No. 09/073,118 was incorporated by reference in the present application, and the addition of FIG. 4E presents no new matter.

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Amendment and Reply

FIG. 4E has been added to the disclosure. This drawing is based on FIG. 11A of the '118 application. A copy of FIG. 11A from the '118 application is included herewith for the

Examiner's convenience as Exhibit B, and is marked up to show the changes made.

Fig. 11A of the '118 application shows the delivery by a steerable catheter of transmyocardial revascularization (TMR) stents. Because those stents were specific to the claims of the '118 application and have no relevance to the claims of the present application, they have been deleted from the FIG. 4E presented here. Reference numerals pertaining to the TMR stents have also been deleted, and parts of the catheter have been provided with numbers as they have been used in the present application. The entire drawing has been rotated 180° to correspond with the depiction of the catheter as it occurs in FIGS. 4A-D.

The specification at page 9 has been amended to include the description of new FIG. 4E. Namely, FIG. 4E includes steerable catheter 36 with pull wire 35, pull wire lumen 37, bond 39 and guidewire 34.

Entry of the new drawing is respectfully requested.

#### Objection to the Claims

Claim 30 was objected to due to an informality. It was been corrected to recite "an elongate shaft slidable through the lumen of the delivery catheter" as suggested in the action.

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Applicants submit that the application is in condition for allowance, which action is requested. Should the examiner believe that further amendments be required, the examiner is invited to telephone the undersigned. Please apply any charges or credits to Deposit Account No. 50-1721.

Respectfully submitted

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After the barbed tip guidewire is anchored in the myocardium, the guide catheter is withdrawn and a steerable stent delivery catheter 106 shown in FIG. 11A is advanced over the guidewire 104 to become positioned within the ventricle for stent delivery. The guidewire lumen 108 of the catheter is oriented eccentrically on the catheter 106. Therefore, when the catheter is rotated about the guidewire 104, the center of the catheter 106 rotates through a circular path 118 as is shown in FIG. 11B to encompass a broader delivery area with one guidewire placement. The outside diameter of the delivery catheter is preferably less than .100".

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Steering capability is provided by a pull wire 122 extending the length of the catheter in lumen 120 and terminating in a bond 124 near the distal tip of the catheter. Pulling the wire 122 from the proximal end causes the more flexible distal tip of the delivery catheter 106 to buckle, thereby providing steering control.

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The deflectable tip catheter 106 has a large central lumen 110 which slidably receives a flexible inner sheath 111. The distal end of the flexible sheath has several resilient fingers 116 located around the circumference of the sheath projecting distally and inwardly toward the center of the lumen to restrain stents 8 loaded within the catheter. Within the inner sheath slides a push wire 114 having a ball 112 near its distal end for engaging the interior of a TMR stent 8

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To deliver the stent 8 into the myocardium, the push rod 114 and inner sheath 111 are advanced distally in unison to move a stent 8 out of the catheter 106 as shown in FIG. 12B. The distal tip of the inner sheath 111 projects slightly from the catheter 106 during delivery. However, It is the push rod 114 and associated ball 112 pushing against the interior of the most proximal stent that continues distally, driving the leading (most distal) stent 8 into the myocardial tissue. However, the stents of the embodiment of FIGS. 3 - 3C cannot be nested due to directing channels formed in their interior and, thus are delivered singularly as shown in Fig. 13. The canted wrapped spring stent embodiment 90 shown in Figs. 9A - 9D, is also delivered singularly, through the delivery catheter, carried over the piercing delivery device 95 shown in Fig. 9C. Rather than being

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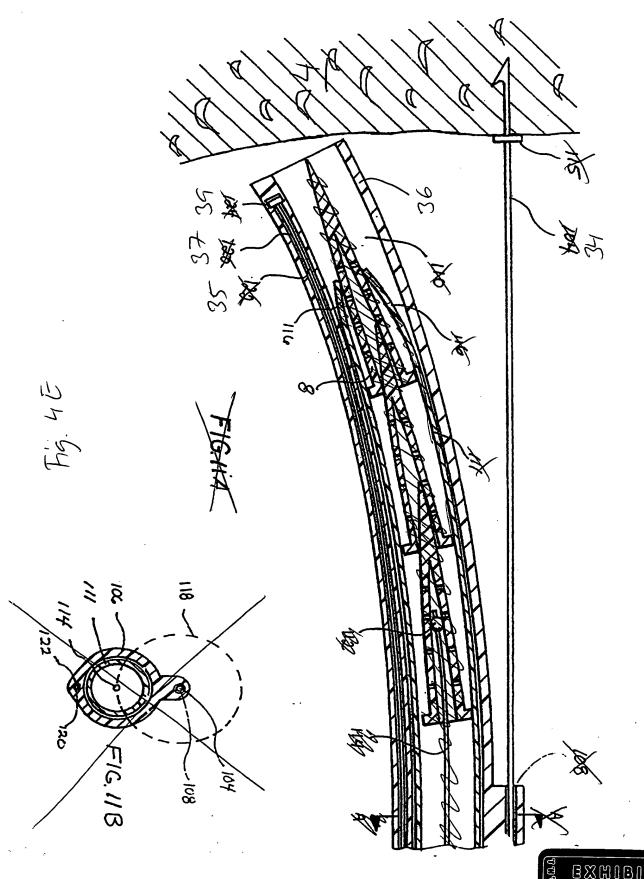


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